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| APPLICATION NO.                 | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---------------------------------|-----------------|----------------------|-------------------------|------------------|
| 09/751,053                      | 12/29/2000      | Daniel W. Gil        | D2919                   | 8979             |
| 33197                           | 7590 09/30/2003 |                      |                         |                  |
| STOUT, UXA, BUYAN & MULLINS LLP |                 |                      | EXAMINER                |                  |
| 4 VENTURE<br>IRVINE, CA         |                 |                      | RILEY, JEZIA            |                  |
|                                 |                 |                      | ART UNIT                | PAPER NUMBER     |
|                                 |                 |                      | 1637                    | 18               |
|                                 |                 |                      | DATE MAILED: 09/30/2003 | •                |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |  | Application No.  | Applicant(s)   |
|--|--|--|--|
|  | Office And O   | 09/751,053   | GIL ET AL.   |
|  | Office Action Summary  | Examiner   | Art Unit   |
|  |  | Jezia Riley  | 1637   |
| Period fo  | The MAILING DATE of this communication apports.  | pears on the c ver sheet with the  | correspondence address   |
| - Exter<br>after<br>- If the<br>- If NO<br>- Failur<br>- Any r | ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a repl period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statute eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).  | 36(a). In no event, however, may a reply be tir<br>y within the statutory minimum of thirty (30) day<br>will apply and will expire SIX (6) MONTHS from | nely filed  s will be considered timely. the mailing date of this communication. |
| 1)⊠  | Responsive to communication(s) filed on 18.  | July 2003 .  |  |
| 2a) <u></u> ☐  | <b>—</b>   | is action is non-final.  |  |
| 3) Disposition   | Since this application is in condition for allows closed in accordance with the practice under on of Claims  | ance except for formal matters of  | rosecution as to the merits is 953 O.G. 213.                                     |
| 4)🛛  | Claim(s) <u>1-21,23-28,30-44 and 68-71</u> is/are pe   | ending in the application.   |  |
|  | 4a) Of the above claim(s) <u>18-21,23,24 and 35</u> i  |  | on.  |
|  | Claim(s) 70 and 71 is/are allowed.   |  |  |
| 6)⊠  | Claim(s) <u>1-17,25,26,30-34,36-44,68 and 69</u> is/   | are rejected.  |  |
|  | Claim(s) <u>27 and 28</u> is/are objected to.  | ,  |  |
|  | Claim(s) <u>1-21,23-28,30-44 and 68-71</u> are subje   | ect to restriction and/or election re  | equirement   |
| Application  | on Papers  |  | rquiroment.  |
| 9)□ T  | he specification is objected to by the Examiner  | ·.   |  |
| 10)∐ T   | he drawing(s) filed on is/are: a)□ accep   | ted or b)□ objected to by the Exar   | niner.   |
|  | Applicant may not request that any objection to the  |  |  |
| 11)∐ T   | he proposed drawing correction filed on  | is: a) ☐ approved b) ☐ disappro  |  |
| _  | If approved, corrected drawings are required in rep  | ly to this Office action.  |  |
| 12)∐ T   | he oath or declaration is objected to by the Exa   | aminer.  |  |
| Priority ur  | nder 35 U.S.C. §§ 119 and 120  |  |  |
| 13) <u> </u>   | Acknowledgment is made of a claim for foreign  | priority under 35 U.S.C. § 119(a)  | -(d) or (f).   |
| a) <u></u>   | ] All b) ☐ Some * c) ☐ None of:  |  |  |
| 1  | Certified copies of the priority documents   | have been received.  |  |
| 2  | 2. Certified copies of the priority documents  | have been received in Application  | n No.  |
|  | B. Copies of the certified copies of the priori<br>application from the International Burd<br>ee the attached detailed Office action for a list of   | ty documents have been received  | d in this National Stage   |
| 14)∐ Ac  | knowledgment is made of a claim for domestic   | priority under 35 U.S.C. & 119/e)  | (to a provisional application)   |
| a) ∣<br>15)∐ Ac  | ☐ The translation of the foreign language provice in the contract of the translation of the translation is made of a claim for domestic in the contract of the contract of the translation.  ☐ The translation of the foreign language provides the contract of the contract of the translation.  ☐ The translation of the foreign language provides the contract of the | isional application has been rece  | ived   |
| Attachment(s   |  | _  |  |
| i)  Notice (   | of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) tion Disclosure Statement(s) (PTO-1449) Paper No(s) <u>16</u>  | 5)   Notice of Informal Da   | PTO-413) Paper No(s)<br>ttent Application (PTO-152)                              |
| Patent and Trade OL-326 (Rev                                   | 04.043   | on Summary   | Part of Paper No. 18   |

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### **DETAILED ACTION**

#### Response to Remarks

1. Applicants' arguments and amendments, filed on 7/18/03, have been approved and entered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

## Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-17, 25, 26, 30-34, 36-44, 68, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinshank et al. (5,595,880) in view of Dolly et al. (WO 95/32738).

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Weinshank discloses DNA encoding a  $\alpha 2B$  adrenergic receptor and uses thereof. The reference discloses a method for determining whether a ligand which is not known to be capable of binding to the .alpha.2b.2B -adrenergic receptor can bind to the .alpha..2B -adrenergic receptor on the surface of a cell, and a method of screening drugs to identify drugs to identify drugs which specifically interact with, and bind to, the .alpha.2B -adrenergic receptor. A method of screening drugs to identify drugs which specifically interact with, and bind to, the .alpha..2B -adrenergic receptor on the surface of a cell is therefore disclosed. This method comprises contacting a mammalian cell which is expressing.alpha..2B -adrenergic receptor with a plurality of drugs, known or putative, determining those drugs which bind to the mammalian cell, and thereby identifying drugs which specifically interact with, and bind to, the .alpha..2B -adrenergic receptor.

Dolly et al. (WO 95/32738) discloses chemical conjugate for treating a nerve cell related disorder. (pages 6-18). This conjugate includes an active or inactive botulinum or tetanus having a specificity for a target nerve cell. The toxin is conjugated to a drug or other bioactive molecule without affecting the toxin's ability to enter the target nerve cell. (Page 2).

Therefore it would have been obvious at the time the invention was made to apply the conjugate of Dolly et al. for the method of screening drugs of the method of Weinshank et al. The motivation is that the conjugate of Dolly et al. is a reconstituted toxin, having an inactivated L chain disulfide –bonded to a native H chain, which retained the ability to specifically interact with target receptors and become transported

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to the cytosol, together with the attached molecule. (page 6) Hence the inactivated and chemically modified toxin complex can be used as a system for delivering linked chemical compounds to the cytosol of neuronal cells that express cell surface receptors for the toxins. (Page 7).

- 4. Claims 27 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 5. Claims 70-71 are allowed.
- 6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JEZIA RILEY PRIMARY EXAMINER